

16. (New) The method according to claim 2, wherein the DNAs sequences are derived from fungi or ascomycetes.
17. (New) The method according to claim 2, wherein the DNAs sequences are derived from the family of hominids or the family of Bovidae.
18. (New) The method according to claim 2, wherein the DNAs sequences are derived from the class of Monocotyledonae.

REMARKS

Claims 1-11 are currently pending. New claims 12-18 have been added and contain subject matter contained in original claims 2 and 8. No new matter has been added.

1. Specification

The Examiner has objected to the Specification because it lacks the section headings required by 37 C.F.R. §1.77. Applicant would like to point out that this section only states that the Specification "should" include various sections. This is not a requirement but merely a recommendation. As such, Applicant has not amended the Specification to include section headings.

The Examiner has also objected to the description of Figure 10 as it does not include a description for figures 10b and 10c. Applicant has amended the Specification to include a description for these figures.

Reconsideration and removal of the objections to the Specification are respectfully requested.

2. Claim Objections

Claim 6 has been objected to for being in improper multiple dependent form. Claim 6 has been amended to correct the improper multiple dependency. Reconsideration and removal of the objection is respectfully requested.

3. Claim Rejections under 35 U.S.C. §112, second paragraph

Claims 1-11 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner states that claims 1 and 11 are indefinite because they recite a use without setting forth the active, positive steps involved in practicing the method. The claims have also been rejected for the use of the phrases "for example", "e.g.", "in particular", "preferably", "most preferably", "such as", "characterized in that", "obtainable", and "derivable". Claims 3-6 have been rejected for lack of antecedent basis for the limitation "the DNAs to be analyzed". Claims 5-6 have been rejected for lack of antecedent basis for the limitation "the DNAs transferred onto a membrane". Claims 9-10 have been rejected for the recitation of a "primer" and the phrase "the primer displays". Claims 9-10 have also been rejected for referring to Tables 1 and 2.

Applicant has amended the independent use claims to set forth the active steps involved in practicing the method. Applicant has also amended the claims to remove the objectionable language identified by the Examiner. Proper antecedent basis support has been provided for the limitations in claims 3-6. Claims 9-10 have been amended to more clearly define the invention and the reference to the tables has been removed. Applicant believes that the foregoing claim amendments

have obviated the indefiniteness rejections. Reconsideration and removal of the rejections is respectfully requested.

4. Claim Rejections under 35 U.S.C. §101

Claims 1-11 have been rejected under 35 U.S.C. §101 for claiming a use without setting forth the steps involved in the process. As noted above, the use claims have been amended to recite the steps involved in practicing the method. Reconsideration and removal of the rejection is respectfully requested.

5. Claim Rejections under 35 U.S.C. §102(b)

A. Claims 1-11 have been rejected under 35 U.S.C. §102(b) as being anticipated by Rohde (Journal of Genetics & Breeding 50:249-261 [9/1996]). The Rohde reference is cited as an anticipatory reference because it allegedly describes the invention and the article was printed or published more than one year prior to the date of the application for patent in the United States. Applicant respectfully submits that the Rohde reference was not printed or published more than one year prior to the date of the application for patent in the United States.

The present application is entitled to a priority date of August 6, 1997. According to the Examiner, the publication date of the Rohde article is September of 1996. This is incorrect. As can be seen from the attached table of contents and the publication imprint from the Journal of Genetics & Breeding, vol. 50 - Number 3, the print of the journal was not finished until the end of April 1997 (See Exhibits 1-3). Applicant would also like to point out that the table of contents indicates that this volume was only made "available to the public" in September of 1998.

For purposes of 35 U.S.C. §102(b), the date of the reference for prior art purposes is the date when the reference is "available to the public". In the present case, the reference could not have been available prior to April of 1997. As such, the Rohde reference does not qualify as prior art under 35 U.S.C. §102(b). Reconsideration and removal of the rejection is, therefore, requested.

B. Claims 1-4 and 10-11 have been rejected under 35 U.S.C. §102(b) as being anticipated by Welsh et al. (Nucleic Acids Res. 18(24):7213-7218[12/1990]). The Examiner argues that Welsh et al. discloses a method for DNA fingerprint analysis in which genomic DNA is PCR amplified using arbitrary primers which can be applied "to any species for which DNA can be prepared". Applicant respectfully disagrees with the conclusions the Examiner has drawn in regards to the teaching of this reference.

Welsh et al. describes "an effective method for preliminary identification of any strain" by an arbitrarily primed PCR (AP-PCR). Welsh et al. points out that:

"For reproducible AP-PCR, many hundreds of template molecules were required under our present conditions. We are investigating conditions that may allow more efficient priming." (see page 7218, left column, lines 41-43).

Moreover, it is noted that:

"we are attempting to develop conditions that will increase the ability of AP-PCR to detect differences in DNA sequences and, thereby, distinguish strains within a species. We are currently experimenting with shorter oligonucleotides and different PCR conditions. A more variable AP-PCR pattern within the species would allow a more detailed picture of intra-specific population

structure." (see page 7218, left column, lines 47-53) (emphasis added).

Thus, Welsh et al describes a method which was still being developed and points out the limitations of their method (i.e. the inability to distinguish different strains within one species). In contrast, the present invention provides a method which allows one to distinguish between separate strains within one species. The sensitivity of the method of the invention is e.g. sufficient to distinguish between homozygous twins as described in detail in example 6 of the Specification. The method of the invention is described in detail and does not require further extensive experimentation to establish conditions which would allow a differentiation between different species as required for the method designated as AP-PCR by Welsh et al. Thus, the surprisingly high sensitivity of the inventive method which makes use of the primers hybridizing with copia-like elements was not described in and could not be expected from the Welsh et al. reference. Reconsideration and removal of the rejection is respectfully requested.

6. *Rejections under 35 U.S.C. §103(a)*

Claim 5 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Rohde in view of Newton (PCR Essential Data, John Wiley & Sons, 1995, p. 104-107). Claim 6 has been rejected over Rohde in view of Newton in further view of Bell (US Patent No. 5,541,060). An obviousness rejection must be based on a combination of "prior art". Prior art is defined under 35 U.S.C. §102. As pointed out above, the Rohde article is not prior art to the present application. As such, Applicant submits that the obviousness rejection of claim 5 over Rohde in view of Newton must

also fall. Reconsideration and removal of these rejections is respectfully requested.

Claim 5 has also been rejected as unpatentable over Welsh et al. in view of Newton. The Examiner argues that Welsch et al. discloses a method of DNA fingerprint analysis in which genomic DNA is amplified using arbitrary primers. Newton is cited for teaching that "immobilization of DNA onto a solid support followed by hybridization to at least one internal probe enhances the sensitivity and characterization of specific product detection compared to gel electrophoresis." The Examiner argues that it would have been obvious to a person of ordinary skill in the art to modify the method of Welsh et al. so as to have included a step of Southern blotting and hybridization of amplification products with a labeled probe. The motivation for the modification, in the Examiner's view, is provided in the enhanced sensitivity of detection as suggested by Newton. Applicant respectfully disagrees.

The present invention is novel and nonobvious over the combination of Welsh et al. in view of Newton. As noted above, Welsh et al. merely represents an "open invitation" to try to establish conditions which may turn out to be suitable for the described AP-PCR. The Welsh et al. reference does not provide any specific teaching or guidance for a person of ordinary skill in the art. Fingerprints, according to Welsch et al., "can be generated using single arbitrarily chosen primers and the polymerase chain reaction. No prior sequence information is required." (see abstract). In contrast, the present ISTR-technology described in the instant Specification, represents a universal method for DNA fingerprint analysis of species selected from all of the different animal kingdoms and genuses. Furthermore, the universality of the method allows one to distinguish between a single strain within one

species and also to distinguish between homozygous twins. This sensitivity is the result of the copia-like element, which is a repetitive sequence in all organisms. The present inventors have, for the first time, described that a primer which hybridizes to a copia-like element of one species may be suitable for single print analysis of all the different organisms described in the application.

The prediction of the suitability of a primer for the inventive method and the universal applicability of the described invention are not disclosed or suggested by Welsch et al. Welsch fails to render the present invention obvious, either singly or in combination with Newton. Accordingly, reconsideration and removal of the rejection is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson (Reg. No. 30,330) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to the provisions of 37 C.F.R. §§1.17 and 1.136(a), the Applicants hereby petition for an extension of three (3) months to November 22, 2002 in which to file a reply to the Office Action. The required fee of \$460.00 is being filed concurrently with this amendment.

Attached hereto is a cleaned-up version of the changes made to the application by this Amendment.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees

Appl. No. 09/485,131

required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment: Cleaned-up Version


(Rev. 02/20/02)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope to: Commissioner of Patents and Trademarks, Washington

D.C. 20231 on:

Nov 22, 2002
(Date of deposit)

BIRCH, STEWART, KOLASCH & BIRCH, LLP


(Signature)

Nov 22, 2002
(Date of Signature)